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(to be used for all correspondence after initial filing)

Application Number	10/054,498
Filing Date	January 22, 2002
First Named Inventor	John Welsh
Group Art Unit	1642
Examiner Name	Hayshemi
Attorney Docket Number	P0026US20

Total Number of Pages in This Submission

7 + \*\*

### ENCLOSURES (check all that apply)

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Remarks

### SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm or Individual name  
Hugh Wang, Reg. No. 47,163

Signature

Date

November 13, 2002

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

John Welsh et al.

Application No.: 10/054,498

Filed: January 22, 2002

For: Genes Overexpressed In Prostate Disorders As Diagnostic And Therapeutic Targets

Examiner: Hayssemi

Art Unit: 1642

Information Disclosure Statement

Assistant Commissioner for Patents  
Washington, D.C. 20231

Sir:

The references cited on attached form PTO/SB/08A are being called to the attention of the Examiner. Copies of the references are enclosed. It is respectfully requested that the cited information be expressly considered during the prosecution of this application, and the references be made of record therein and appear among the "references cited" section on any patents to issue therefrom.

As provided for by 37 CFR 1.97(g) and (h), no inference should be made that the information and references cited are prior art merely because they are in this statement, and no representation is being made that a search has been conducted or that this statement encompasses all the possible relevant information.

Applicants believe that no fee is required for submission of this statement, since it is being submitted prior to the first Office Action. However, if a fee is required, the Commissioner is authorized to deduct such fee from the undersigned's Deposit Account No.:

50-1885. Please deduct any additional fees from, or credit any overpayment to, the above-noted Deposit Account.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'H. Wang', with a stylized flourish extending to the right.

Hugh Wang  
Reg. No. 47,163

Genomics Institute of the Novartis Research Foundation  
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Tel: (858) 812-1500  
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Substitute for form 1449A/PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Sheet

1

of

4

**Complete if Known**

Application Number	10/054,498
Filing Date	January 22, 2002
First Named Inventor	John Welsh
Group Art Unit	1642
Examiner Name	Hayshemi
Attorney Docket Number	P0026US20

**U.S. PATENT DOCUMENTS**

Examiner Initials *	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
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**FOREIGN PATENT DOCUMENTS**

Examiner Initials *	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Country Code <sup>3</sup> - Number <sup>4</sup> - Kind Code <sup>5</sup> (if known)				
	AA	WO 01/34802 A2	May 17, 2001	Corxia Corp.		

**OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS**

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	AB	BOOTCOV et al., Proc. Natl. Acad. Sci. USA, Vol. 94, No. 21, pp. 11514-11519 (1997); MIC-1, a novel macrophage inhibitory cytokine, is a divergent member of the TGF- superfamily.	
	AC	BRAWER, Semin. Surg. Oncol. 18: 3-9, 2000; Prostate-specific antigen.	
	AD	BRAWER et al., Am. J. Clin. Pathol. 92: 760-764, 1989; Serum prostate-specific antigen and prostate pathology in men having simple prostatectomy.	
	AE	BUSSEMAKERS et al., Cancer Res., Vol. 59, pp. 5975-5979 (1999); DD3: a new prostate-specific gene, highly overexpressed in prostate cancer.	
	AF	CATALONA et al., JAMA 270:948-954, 1993; Detection of organ-confined prostate cancer is increased through prostate-specific antigen-based screening.	
	AG	CHANG et al., Cancer Res., Vol. 57, pp. 4075-4081 (1997); Differentially expressed genes in androgen-dependent and -independent prostate carcinomas.	

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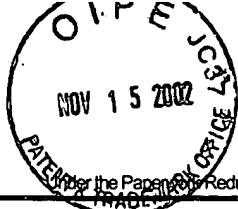
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<sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

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		First Named Inventor	John Welsh
		Group Art Unit	1642
		Examiner Name	Hayshemi
		Attorney Docket Number	P0026US20
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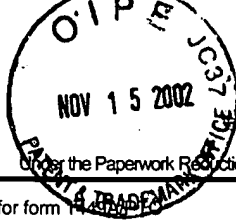
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	AH	CHOO et al., Prostate, Vol. 40, pp. 150-158 (1999); Immortalization of human prostate epithelial cells by HPV 16 E6/E7 open reading frames.	
	AI	DHANASEKARAN et al., Nature 412: 822-826 (2001); Delineation of prognostic biomarkers in prostate cancer.	
	AJ	EMMERT-BUCK et al., Am. J. Pathol., Vol. 156, pp. 1109-1115 (2000); Molecular Profiling of Clinical Tissue Specimens: Feasibility and Applications	
	AK	FERDINANDUSSE et al., J Lipid Res 2000 Nov;41(11):1890-6; Subcellular localization and physiological role of alpha-methylacyl-CoA racemase.	
	AL	HOANG et al., Am. J. Pathol., Vol. 156, pp. 857-864 (2000); A novel association between the human heat shock transcription factor 1 (HSF1) and prostate adenocarcinoma.	
	AM	HROMOS et al., Biochim. Biophys. Acta. Vol. 1354, No. 1, pp. 40-44 (1997); PLAB, a novel placental bone morphogenetic protein.	
	AN	HUANG et al., Genomics, Vol. 59, pp. 178-186 (1999); Prostate Cancer Expression Profiling by cDNA Sequencing Analysis.	
	AO	JIANG et al., Am. J. Surg. Pathol. 25: 1397-1404, 2001; P504S: a new molecular marker for the detection of prostate carcinoma.	
	AP	KANNAN et al., FEBS Lett., Vol. 470, No. 1, pp. 77-82 (2000); Profile of gene expression regulated by induced p53: connection to the TGF- family.	
	AQ	KAZAMA, J. Biol. Chem., Vol. 270, pp. 66-72 (1995); Hepsin, a Putative Membrane-associated Serine Protease, Activates Human Factor VII and Initiates a Pathway of Blood Coagulation on the Cell Surface Leading to Thrombin Formation.	
	AR	KUHAJDA, in Nutrition, Vol. 16, No. 3, pp. 202-208 (2000); Fatty-acid synthase and human cancer: new perspectives on its role in tumor biology.	
	AS	LALANI et al., Cancer Metastasis Rev., Vol. 16, pp. 29-66 (1997); Molecular and cellular biology of prostate cancer.	

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Sheet 3 of 4

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Application Number	10/054,498
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First Named Inventor	John Welsh
Group Art Unit	1642
Examiner Name	Hayshemi
Attorney Docket Number	P0026US20

### OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS

Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	AT	LI et al., Science, Vol. 275, pp. 1943-1947 (1997); PTEN, a Putative Protein Tyrosine Phosphatase Gene Mutated in Human Brain, Breast, and Prostate Cancer	
	AU	LUO et al., Cancer Res. 61: 4683-88, 2001; Human prostate cancer and benign prostatic hyperplasia: molecular dissection by gene expression profiling.	
	AV	MAGEE et al., Cancer Res. 61: 5692-96, 2001; Expression profiling reveals hepsin overexpression in prostate cancer.	
	AW	MARCELLI et al., Cancer Res., Vol. 60, pp. 944-949 (2000); Androgen receptor mutations in prostate cancer.	
	AX	MIKI et al., PNAS 98: 2199-2204, 2001; Delineating developmental and metabolic pathways in vivo by expression profiling using the RIKEN set of 18,816 full-length enriched mouse cDNA arrays.	
	AY	NAM et al., J. Clin. Oncol. 18: 1036-1042, 2000; Serum human glandular kallikrein-2 protease levels predict the presence of prostate cancer among men with elevated prostate-specific antigen.	
	AZ	PILARSKY et al., Prostate, Vol. 36, pp. 85-91 (1998); Expression of the extracellular matrix signaling molecule Cyr61 is downregulated in prostate cancer.	
	BA	PIZER et al., Prostate 2001 May 1;47(2):102-10; Increased fatty acid synthase as a therapeutic target in androgen-independent prostate cancer progression.	
	BB	SUN et al., Cancer Res., Vol. 57, pp. 18-23 (1997); Human prostatic carcinoma oncogene PTI-1 is expressed in human tumor cell lines and prostate carcinoma patient blood samples.	
	BC	SCHER et al., Urology 55: 323-327, 2000; Clinical states in prostate cancer: toward a dynamic model of disease progression.	
	BD	SAFFRAN et al., Cancer Metastasis Rev. 18: 437-449 (1999); Target antigens for prostate cancer immunotherapy.	

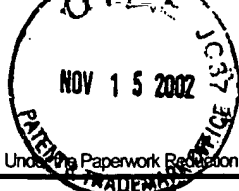
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	BE	STAMEY et al., J. Urol. 166: 2171-77, 2001; Molecular genetic profiling of Gleason grade 4/5 prostate cancers compared to benign prostatic hyperplasia.	
	BF	TANIMOTO et al., Cancer Res., Vol. 57, pp. 2884-2887 (1997); Hepsin, a cell surface serine protease identified in hepatoma cells, is overexpressed in ovarian cancer.	
	BG	TORRES-ROSADO et al., Proc. Natl. Acad. Sci. USA, Vol. 90, pp. 7181-7185 (1993); Hepsin, a Putative Cell-Surface Serine Protease, is Required for Mammalian Cell Growth.	
	BH	TSUJI et al., J. Biol. Chem., Vol. 266, pp. 16948-16953 (1991); Hepsin, a cell membrane-associated protease. Characterization, tissue distribution, and gene localization.	
	BI	VOELLER et al., Cancer Res., Vol. 58, pp. 2520-2523 (1998); Beta-catenin mutations in human prostate cancer.	
	BJ	VU et al., J. Biol. Chem., Vol. 272, pp. 31315-31320 (1997); Identification and Cloning of the Membrane-associated Serine Protease, Hepsin, from Mouse Preimplantation Embryos.	
	BK	WU et al., J. Clin. Invest., Vol. 101, pp. 321-326 (1998); Generation and characterization of mice deficient in hepsin, a hepatic transmembrane serine protease.	
	BL	YANG et al., Cancer Res., Vol. 58, pp. 3732-3735 (1998); Identification of genes expressed differentially by LNCaP or PC-3 prostate cancer cell lines.	

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